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Pierre Fabre
MEDICAL DEVICES

510(K) SUMMARY
PIERRE FABRE DEXERYL™ CREAM

SUBMITTER AND OWNER

Pierre Fabre Medical Devices
Les Fontaines
29 avenue du Sidobre
81106 Castres Cedex
France
Attn.: M. Pascal Lefrançois

Date Prepared: 30 January 2012

DEVICE NAME

Trade Name:	DEXERYL™ Cream
Common Name:	Wound dressing
Classification Name:	Dressing, Wound, Drug
Regulation No.:	Unclassified
Procode:	FRO

PREDICATE DEVICES

DEXERYL™ Cream is substantially equivalent in composition and intended use to the following legally marketed devices in commercial distribution:

- Tropazone Cream (K093544),
- Neosalus (K090585),
- Tetrix Cream (K071483),
- EpiCeram (K052643) and
- Biafine (K964240).

DEVICE DESCRIPTION

DEXERYL™ Cream is a clean but non-sterile skin emollient designed to provide protection and a moist environment to the skin, which is beneficial to the healing process. DEXERYL™ Cream is an oil in water emulsion, consisting of >50% water with glycerin, white soft paraffin, liquid paraffin, and other common excipients.

The device formulation therefore confers an emollient effect, softening and soothing the skin to help prevent dry skin, irritation and itching. DEXERYL™ Cream is a prescription device.

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MEDICAL DEVICES

INTENDED USE

DEXERYL™ Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses including atopic dermatitis, allergic contact dermatitis and irritant contact dermatitis. DEXERYL™ Cream provides a moist environment, which is beneficial to the healing process.

COMPARISON OF TECHNOLOGICAL FEATURES

DEXERYL™ Cream is similar in design, intended use, and technological characteristics to the predicate devices and existing wound dressings that have been cleared for US commercial distribution. The device is an emulsified semi-viscous cream intended for topical use, similar to the predicate devices in composition and in intended use.

SUMMARY OF TESTING DATA

Device safety has been demonstrated through biocompatibility testing in conformance with recommendations of ISO 10993-1, and clinical testing and extensive clinical use in Europe. The minor differences in material constituents between DEXERYL™ Cream and the predicates are adequately addressed by the testing completed on the product and the clinical experience with the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pierre Fabre Medical Devices
% The Weinberg Group, Inc.
Diane Horwitz, Ph.D.
1129 Twentieth Street, Northwest
Washington, District of Columbia 20036

MAR - 7 2012

Re: K113807
Trade/Device Name: DEXERYL™ Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 22, 2011
Received: December 23, 2011

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

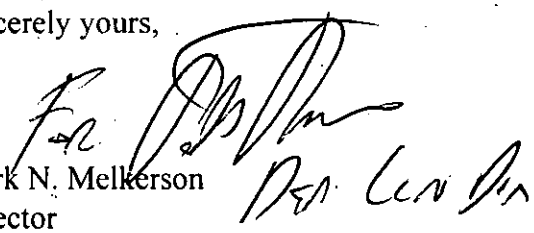
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113807

Device Name: DEXERYL™ Cream

Indications for Use:

DEXERYL™ Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses including atopic dermatitis, allergic contact dermatitis and irritant contact dermatitis. DEXERYL™ Cream provides a moist environment, which is beneficial to the healing process.

Prescription Use X AND/OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krueger MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113807